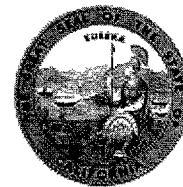


State of California—Health and Human Services Agency  
**Department of Health Services**



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**ARNOLD SCHWARZENEGGER**  
Governor

March 1, 2004

Food and Drug Administration  
Division of Dockets Management (HFA-305)  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**GUIDANCE LEVELS FOR RADIONUCLIDES IN DOMESTIC AND IMPORTED  
FOODS; DOCKET NUMBER 2003D-0558**

Dear Sir or Madam:

Thank you for the opportunity to comment on the subject document. The California Department of Health Services, Radiologic Health Branch (DHS/RHB) agrees that the proposed Derived Intervention Levels (DILs) in the subject document generally represent more scientifically defensible guidance levels than the Levels of Concern established in the FDA's Compliance Policy Guide 7119.14 (1986). However, the addition of guidance levels for plutonium-238 (Pu-238), plutonium-239 (Pu-239) and americium-241 (Am-241) may present insurmountable practical problems, due to the difficulty in measuring the recommended DILs in foodstuffs.

In a 1995 survey of commercial analytical radiochemistry laboratories regarding their detection levels for various radionuclides, the laboratories reported lower limits of detection for Pu-238 and Pu-239 of between 0.74 – 14.8 becquerel per kilogram (Bq/kg), and for Am-241 of between 1.8 and 18.5 Bq/kg.<sup>1</sup> Although the reported ranges encompass the DIL of 2 Bq/kg proposed for these radionuclides, as a practical matter, detecting these levels will be extremely costly and time-consuming, and the level of confidence in the results may be low due to the expected variance in sample results for a single lot of foodstuffs.

The International Atomic Energy Agency (IAEA) recently convened a panel of experts. Their recommendations were published the "Proposed Draft Revised Guideline Levels for Radionuclides in Foods for Use in International Trade," (January 22, 2004). The recommendations include a guidance level of 10 Bq/kg for Pu-238, Pu-239 and Am-241. While the detection of this level will still be costly, time-consuming and difficult, the effort required will be less and the reliability of the results greater for detection of this level than the current proposed DIL. In addition, adoption of their recommendation will provide international consistency.

<sup>1</sup>F.M. Cox and C.F. Guenther, "An Industry Survey of Current Lower Limits of Detection for Various Radionuclides," Health Physics Journal, Volume 69, Number 1 (July 1995).

**2003D-0558**

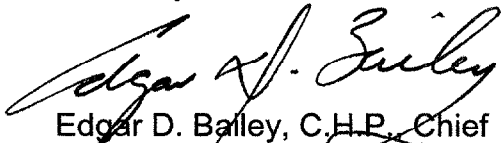
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Page 2  
March 1, 2004

According to the IAEA draft guidance, a level of 10 Bq/kg would result in a dose of less than 1 milliSievert per year, committed effective dose equivalent, based on an assumption that only 10% of the food supply is contaminated at this level and using more recent dosimetric models than those supporting FDA's current proposal. In short, using FDA's more conservative estimate of contaminated foods (i.e., 30% of the food supply), and using the more recent dosimetric models, the committed effective dose equivalent would still be less than the Protective Action Guideline of 5 milliSievert per year.

In conclusion, DHS/RHB supports the proposed DILs, with the exception of those proposed for Pu-238, Pu-239 and Am-241. In the alternative, for these three radionuclides, DHS/RHB recommends the adoption of a DIL of 10 Bq/kg, as recommended by the IAEA panel.

Sincerely,

A handwritten signature in black ink, appearing to read "Edgar D. Bailey". The signature is fluid and cursive, with the first name "Edgar" being more prominent.

Edgar D. Bailey, C.H.P., Chief  
California Department of Health Services  
Radiologic Health Branch